JAN 3 2013

510(k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Junctional Emergency Treatment Tourniquet is provided below.

Date Summary Prepared	December 14, 2012
Manufacturer/Distributor/Sponsor	North American Rescue 35 Tedwall Court Greer, SC 29650-4791 USA
510(k) Contact	North American Rescue, LLC William Slevin 35 Tedwall Court Greer, SC 29650-4791 864-275-9300 (phone) wslevin@narescue.com (email)
Trade Name	*Junctional Emergency Treatment Tool*
Common Name	Vascular Clamp
Code –Name –Classification	**DXC** – Vascular Clamp 21 CFR 870.4450: Class II
Predicate Devices	Combat Ready Clamp K102025
Device Description	Device Description: The Junctional Emergency Treatment Tool is designed to be used by first responders for emergent purposes. The device is designed to control bleeding in the inguinal area where standard tourniquets cannot be used. The device can be used instead of manual pressure, allowing the healthcare provider to attend to other casualties. The Junctional Emergency Treatment Tool is used to control a difficult bilateral or unilateral bleeding for up to 4 hours until the casualty can be transferred for treatment. The Junctional Emergency Treatment Tool consists of a belt assembly, with two trapezoidal pressure pads and Threaded T-Handles. The two pressure pads allow the provider to treat a casualty with either unilateral or bilateral injuries.
Intended Use	The *North American Rescue Junctional Emergency Treatment Tool* is indicated for emergent purposes to control difficult bleeds in the inguinal area.
Technological Characteristics	The Junctional Emergency Treatment Tool employs trapezoidal pressure pads with threaded T-handles to occlude the femoral artery. The Junctional Emergency Treatment Tool is attached with a nylon belt and locking mechanism. Additionally, a comparative bench top test was performed showing the forces applied by the Junctional Emergency Treatment Tool and the predicate are equivalent.
Non-Clinical Performance Testing Conclusion	The Junctional Emergency Treatment Tool was tested with a cadaveric model to demonstrate it was consistently capable of stopping simulated vessel blood flow, both in unilateral and bilateral hemorrhage control. The Junctional Emergency Treatment Tool was tested in Non-Clinical Bench Top Testing to demonstrate it was consistently capable of applying forces equivalent to the predicate device.
Substantial Equivalence Summary (Conclusion)	Based on the technological; characteristics and non-clinical performance testing the Junctional Emergency Treatment Tool was shown to be substantially equivalent to the predicate device, the Combat Ready Clamp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

North American Rescue Products, LLC
c/o Mr. William Slevin
35 Tedwall Court
Greer, SC 29650-4791

JAN 3 2013

Re: K123194
Trade/Device Name: Junctional Emergency Treatment Tool
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 18, 2012
Received: December 20, 2012

Dear Mr. Slevin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123194

Device Name: ***Junctional Emergency Treatment Tool***

The *North American Rescue Junctional Emergency Treatment Tool* is indicated for emergent purposes to control difficult bleeds in the inguinal area.

Prescription Use X AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123194